UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,494	06/11/2001	Jeffrey Harris	27779/35932	3941

7590 07/02/2002

David W. Clough, P.h.D.
KATTEN MUCHIN ZAVIS ROSENMAN
Suite 1600
525 West Monroe Street
Chicago, IL 60661-3693

EXAMINER
HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/787,494	Applicant(s) HARRIS ET AL.	
	Examiner " Neon" Phuong Huynh	Art Unit 1644	

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-58* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Fax cover sheet* .

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Claims 1-58 are pending.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

I. Claims 1-11, drawn to a composition comprising β **human chorionic gonadotropin protein (βhCG),** fragments or analogs thereof, chitosan-based adjuvant, and wherein the recombinant polypeptide further comprises the amino acid sequence of **SEQ ID NO: 2**.

II. Claims 1-11, drawn to a composition comprising β **human chorionic gonadotropin protein (βhCG),** fragments or analogs thereof, chitosan-based adjuvant, and wherein the recombinant polypeptide further comprises the amino acid sequence of **SEQ ID NO: 4**.

III. Claims 1-10, and 12, drawn to a composition comprising β human chorionic gonadotropin **(βhCG) fusion protein** wherein the recombinant fusion protein consisting of **βhCG protein,** fragment or analog **joined to a β-galactosidase protein** or fragment thereof, chitosan-based adjuvant and further comprises the amino acid sequence of **SEQ ID NO: 2**.

IV. Claims 1-10, and 12, drawn to a composition comprising β human chorionic gonadotropin **(βhCG) fusion protein** wherein the recombinant fusion protein consisting of **βhCG protein,** fragment or analog **joined to a β-galactosidase protein** or fragment thereof, chitosan-based adjuvant and further comprises the amino acid sequence of **SEQ ID NO: 4**.

V. Claims 1-12, drawn to a composition comprising β human chorionic gonadotropin protein **(βhCG) and fusion protein** wherein the recombinant fusion protein consisting of **βhCG protein,** fragment or analog **joined to a β-galactosidase protein** or fragment thereof, in combination with chitosan-based adjuvant, and further comprises the amino acid sequence of **SEQ ID NO: 2**.

VI. Claims 1-12, drawn to a composition comprising β human chorionic gonadotropin protein **(βhCG) and fusion protein** wherein the recombinant fusion protein consisting of **βhCG protein,** fragment or analog **joined to a β-galactosidase protein** or fragment thereof, in combination with chitosan-based adjuvant, and further comprises the amino acid sequence of **SEQ ID NO: 4**.

VII. Claims 13-23, 25-34, and 36-45, drawn to **a method of inducing infertility** in a female mammal comprising administering a vaccine containing a recombinant human chorionic **gonadotropin protein (βhCG)**, fragments or analogs thereof in combination with a chitosan-based adjuvant in an amount effective to stimulate production of antibodies which recognize native circulating hGC proteins and further comprises the amino acid sequence of **SEQ ID NO: 2**.

VIII. Claims 13-23, 25-34, and 36-45, drawn to **a method of inducing infertility** in a female mammal comprising administering a vaccine containing a recombinant human chorionic **gonadotropin protein (βhCG)**, fragments or analogs thereof in combination with a chitosan-based adjuvant in an amount effective to stimulate production of antibodies which recognize native circulating hGC proteins and further comprises the amino acid sequence of **SEQ ID NO: 4**.

IX. Claims 13-46, drawn to **a method of inducing infertility** in a female mammal comprising administering a vaccine containing a β human chorionic gonadotropin **(βhCG) fusion protein** wherein the recombinant fusion protein consisting of **βhCG protein,** fragment or analog **joined to a β-galactosidase protein** or fragment thereof, in

combination with a chitosan-based adjuvant in an amount effective to stimulate production of antibodies which recognize native circulating hGC proteins and further comprises the amino acid sequence of **SEQ ID NO: 2**.

X. Claims 13-46, drawn to **a method of inducing infertility** in a female mammal comprising administering a vaccine containing a β human chorionic gonadotropin **(βhCG) fusion protein** wherein the recombinant fusion protein consisting of **βhCG protein,** fragment or analog **joined to a β-galactosidase protein** or fragment thereof, in combination with a chitosan-based adjuvant in an amount effective to stimulate production of antibodies which recognize native circulating hGC proteins and further comprises the amino acid sequence of **SEQ ID NO: 4**.

XI. Claims 13-46, drawn to **a method of inducing infertility** in a female mammal comprising administering a vaccine containing β human chorionic gonadotropin protein **(βhCG) and fusion protein,** wherein the recombinant fusion protein consisting of **βhCG protein,** fragment or analog **joined to a β-galactosidase protein** or fragment thereof, in combination with a chitosan-based adjuvant in an amount effective to stimulate production of antibodies which recognize native circulating hGC proteins and further comprises the amino acid sequence of **SEQ ID NO: 2**.

XII. Claims 13-46, drawn to **a method of inducing infertility** in a female mammal comprising administering a vaccine containing β human chorionic gonadotropin protein **(βhCG) and fusion protein,** wherein the recombinant fusion protein consisting of **βhCG protein,** fragment or analog **joined to a β-galactosidase protein** or fragment thereof, in combination with a chitosan-based adjuvant in an amount effective to stimulate production of antibodies which recognize native circulating hGC proteins and further comprises the amino acid sequence of **SEQ ID NO: 4.**

XIII. Claims 47-57, drawn to a method of using βhCG for the manufacture of a medicament for inducing transient infertility in a mammal wherein the medicament comprises an injectable formulation of **βhCG,** fragments or analogs thereof in combination with chitosan-based adjuvant in an amount effective to stimulate production of antibodies which recognize native circulating hCG proteins and further comprises the amino acid sequence of **SEQ ID NO: 2**.

XIV. Claims 47-57, drawn to a method of using βhCG for the manufacture of a medicament for inducing transient infertility in a mammal wherein the medicament comprises an

injectable formulation of **βhCG,** fragments or analogs thereof in combination with chitosan-based adjuvant in an amount effective to stimulate production of antibodies which recognize native circulating hCG proteins and further comprises the amino acid sequence of **SEQ ID NO: 4**.

XV. Claims 47-53 and 55-58, drawn to a method of using βhCG for the manufacture of a medicament wherein the medicament comprises an injectable formulation of β human chorionic gonadotropin **(βhCG) fusion protein** wherein the recombinant fusion protein consisting of **βhCG protein,** fragment or analog **joined to a β-galactosidase protein** or fragment thereof, in combination with chitosan-based adjuvant in an amount effective to stimulate production of antibodies which recognize native circulating hCG proteins and further comprises the amino acid sequence of **SEQ ID NO: 2**.

XVI. Claims 47-53 and 55-58, drawn to a method of using βhCG for the manufacture of a medicament wherein the medicament comprises an injectable formulation of β human chorionic gonadotropin **(βhCG) fusion protein** wherein the recombinant fusion protein consisting of **βhCG protein,** fragment or analog **joined to a β-galactosidase protein** or fragment thereof, in combination with chitosan-based adjuvant in an amount effective to stimulate production of antibodies which recognize native circulating hCG proteins and further comprises the amino acid sequence of **SEQ ID NO: 4**.

XVII. Claims 47-58, drawn to a method of using βhCG for the manufacture of a medicament wherein the medicament comprises an injectable formulation of β human chorionic gonadotropin protein **(βhCG) and fusion protein** wherein the recombinant fusion protein consisting of **βhCG protein,** fragment or analog **joined to a β-galactosidase protein** or fragment thereof, in combination with chitosan-based adjuvant in an amount effective to stimulate production of antibodies which recognize native circulating hCG proteins and further comprises the amino acid sequence of **SEQ ID NO: 2**.

XVIII. Claims 47-58, drawn to a method of using βhCG for the manufacture of a medicament wherein the medicament comprises an injectable formulation of β human chorionic gonadotropin protein **(βhCG) and fusion protein** wherein the recombinant fusion protein consisting of **βhCG protein,** fragment or analog **joined to a β-galactosidase protein** or fragment thereof, in combination with chitosan-based adjuvant in an amount

effective to stimulate production of antibodies which recognize native circulating hCG proteins and further comprises the amino acid sequence of **SEQ ID NO: 4**.

The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The EP0368,253 patent (of record, Partain et al, May 1990, PTO 1449) teaches a composition of instant claim 1 comprising β human chorionic gonadotropin protein (βhCG) (see column 10, lines 37-39, in particular) and chitosan-based adjuvant (See column 2, lines 32-37, column 9, lines 28-37 and column 9, lines 37-43).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

5. Accordingly, Groups I-XVIII are not so linked as to form a single general inventive concept and restriction is proper.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
July 1, 2002

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600